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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,281	06/06/2001	Anthony Viole	FORFLOW.008A	8796
75	90 03/09/2004		EXAM	INER
Knobbe< Martens, Olson & Bear, LLP			BOCKELMAN, MARK	
620 Newport Ce			I DE LOUIS	D . DCD . W. LDCD
Sixteenth Floor Newport Beach, CA 92660			ART UNIT	PAPER NUMBER
			3762	18
		DATE MAILED: 03/09/2004		

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summan.		Application No.	Applicant(s)		
		09/876,281	VIOLE ET AL.		
i``	Office Action Summary	Examiner	Art Unit		
		Mark W Bockelman	3762		
Period 1	The MAILING DATE of this communication app for Reply	pears on the cover sheet with the	e correspondence address		
THE - Ext - If th - If N - Fai - Any	HORTENED STATUTORY PERIOD FOR REPL' MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.1 er SIX (6) MONTHS from the mailing date of this communication. eperiod for reply specified above is less than thirty (30) days, a reply o period for reply is specified above, the maximum statutory period valure to reply within the set or extended period for reply will, by statute or reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be y within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS fr , cause the application to become ABANDO	e timely filed  days will be considered timely.  om the mailing date of this communication.  NED (35 U.S.C. § 133).		
1)[🗆	Responsive to communication(s) filed on <u>Dec</u>	ccember 22, 2003 .			
2a)□	This action is <b>FINAL</b> . 2b)⊠ Th	is action is non-final.			
3)⊡ Disposi	Since this application is in condition for allows closed in accordance with the practice under tion of Claims				
4)⊠	Claim(s) 1-50 is/are pending in the application	1.	•		
	4a) Of the above claim(s) 3,13-26,31-37,42,46	.49 <b>4</b> is/are withdrawn from cor	nsideration.		
5)	Claim(s) is/are allowed.				
6)⊠ Claim(s) <u>1,2,4-12,27-30,38-41,43-45,47,48 and 50</u> is/are rejected.					
7)	Claim(s) is/are objected to.				
8)⊡ Applica	Claim(s) are subject to restriction and/o	r election requirement.			
9)[_	The specification is objected to by the Examine	r.			
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
	Applicant may not request that any objection to th	* * * *	•		
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12)	The oath or declaration is objected to by the Ex	aminer.			
Priority	under 35 U.S.C. §§ 119 and 120				
13)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119	9(a)-(d) or (f).		
а	) All b) Some * c) None of:				
	1. Certified copies of the priority document	s have been received.			
	2. Certified copies of the priority document	s have been received in Applic	ation No		
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
	Acknowledgment is made of a claim for domesti	·			
· _	a)      The translation of the foreign language pro Acknowledgment is made of a claim for domest	ovisional application has been r	received.		
Attachme	-		•		
2) 🔲 Not	ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u>	5) 🔲 Notice of Inform	nary (PTO-413) Paper No(s) al Patent Application (PTO-152)		

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### **DETAILED ACTION**

## Claim Rejections - 35 USC § 112

Claims 27 –30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers the pump speed back to an unspecified patient and an up specified flow rate of the person. Since these parameters vary from person to person, the datum point is indefinite as well as the claim.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 ,2and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Aigner USPN 4,540,402.

See page 3 of the office action mailed 12-31-02

Claims 1, 5, 6, 8 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Marhurkar USPN 4,134,402.

See page 4 of the office action dated 12-31-02

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Claims 1, 11,12 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant USPN 5,618,267.

See page 4 of the office action dated 12-31-02

Claims 1-2, 4, 6-8, 12, 38-41, 43-45, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Runge USPN 5,785,686.

Runge teaches a catheter with first and second distal ends with a first end being shown at 11a and the second being at location 12 at it's tapered end. Runge has several apertures, extending from the distal end to "near" the proximal end. These aperatures will also drawn or deliver fluids to aid in perfusing (depending on how the device is inserted into the body) in the same fashion as applicant's means and are thus considered equivalents. The catheter is connected to a pump by inflow and outflow conduits 3 and 4. The catheter is fully capable of performing applicant's statements of intended use, which statements are otherwise given little or no patentable weight. The examiner considers the branch portion of the catheter to be a y-connector and to serve as an indicator when inserting the catheter. The examiner notes that the Runge catheter is capable of being operated without inflating the balloons.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Runge. Applicant's relation to the stated persons flow rate is considered indefinite as explained above. The flow rate of the Runge device, if it is set to a specific rate, will inherently be less than some people and would meet the claim. Alternatively, to have provided the pump with a flow control to adjust the rate to a various people would have been notoriously old and well known since pumps are conventionally equipped with such.

Claims 5, 9-11, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Runge. Applicant differs from Runge in reciting a tapered tip at the first distal end, a radiopaque marker and a j-tip. Arguably the Runge ference shows a J- configuration, however it is believed that the claim is limited to preformed tips. Nevertheless, each of these elements are conventional items for assisting the insertion of the catheter into the body and to have included such configurations to Runge to aid in inserting it into the heart would have been obvious.

#### Response to Arguments

Applicant's arguments filed 12-22-03 have been fully considered but they are not persuasive. Applicant's functional language with respect to the catheter calims does not adequately define over the references simply because it depends on what one calls the "cannulation site". Certainly if one calls the point of entry (incision) the cannulation site, the applied references still meet the claim. Likewise, one could consider the points adjacent to the ports to be the cannulation site for claim 50. Applicant is again relying upon unspecified body regions and parameters that offer little distinguishing structure to the claims. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MilBell

MWB

March 4, 2004